JUL 2 6 2013

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SDMA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K130785

1. **Submitter's Identification:**

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Regulatory Affairs Manager
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Date Summary prepared: 2013-03-19

2. **Name of the Device:** SEER 1000

3. **Device Class:** Class II

4. **Common or Usual Name:** Holter ECG recorder without Analysis

5. **Predicate Device Information:**

Device	Manufacturer	510(k) Number
SEER Light Extend Compact Digital Holter System	GE Medical Systems Information Technologies	K050731
CardioMem® CM 3000-12BT	GETEMED Medizin- und Informationstechnik AG	K063042

6. Device Description:

The SEER 1000 Holter recorder is designed to acquire ambulatory 2 or 3 channels of ECG signal from the chest surface of patients for up to 7 days. The device stores the acquired ECG data in its on-board flash memory. Patient demographic information can be downloaded from a PC application or from a mobile application (IPhone, IPod, IPad) into the SEER 1000 recorder via Bluetooth during hookup time. With the PC application or mobile application you can start or stop a recording and you can check signal quality of the ECG data during hookup time or recording. At the end of the recording, the SEER 1000 can be directly connected to a PC via an USB cable to download the recorded data for later evaluation. It is not possible to connect an USB cable and an ECG patient cable to the recorder at the same time.

7. Intended Use:

The SEER 1000 digital Holter recorder is intended to continuously record ECG data. The SEER 1000 performs no cardiac analysis by itself and is intended to be used with an ECG analysis software package. The recorded data are downloaded to a PC for analysis and subsequent evaluation by a trained physician or health care professional.

8. Comparison to Predicate Devices:

The SEER 1000 Holter recorder is substantially equivalent to the Holter recorder CardioMem® CM 3000-12BT (K063042) from GETEMED Medizin- und Informationstechnik AG and the SEER Light Extend Compact Digital Holter System (K050731) from GE Medical Systems Information Technologies. All Holter recorders record ECG data and don't perform cardiac analysis by themselves. Only some incremental changes in the SEER 1000 were made to improve the usability, the design and to bring the technical details up-to date. Wireless technology is used in the SEER Light (infrared) and CM 3000-12BT and the SEER 1000 (Bluetooth) to transfer patient data and to check the signal quality of ECG data during hookup time and recording. The SEER Light and the SEER 1000 have to be connected to a PC to read out the recorded ECG data for later evaluation. The SEER 1000 design (device without display) and operating principle (handling) is identical to the SEER Light. The SEER Light Extend Controller and the SEER 1000 PC and mobile application are both used to transfer patient data and to check the signal quality of ECG data. No influence on safety and effectiveness has been found.

9. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Non-clinical testing that has been conducted includes:
a. Electromagnetic compatibility evaluation according to IEC 60601-1-2;
b. Electrical safety test according test to IEC 60601-1
c. ECG performance test according to AAMI ANSI EC 38

None of the testing demonstrated that the SEER 1000 brought up any issues of safety or effectiveness.

10. **Discussion of Clinical Tests Performed:**

No clinical testing was performed in order to support safety or effectiveness.

11. **Conclusion:**

The Holter recorder SEER 1000 is identical in indications for use to its predicate device and very similar in functionality, design, material and performance to applicable standards. The main modification is the implementation of the Bluetooth wireless technology as used in the CM 3000-12BT instead infrared as used in the SEER Light. Generally, there was a process of miniaturization for the complete device, so that it is now smaller and lighter.

The test results in this submission demonstrated that these small differences do not raise any new questions of safety and effectiveness to the subject device and the subject device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 26, 2013

GETEMED Medizin-und Informationstechnik AG
c/o Dr. Bert Schadow
Regulatory Affairs Manager
Oderstr. 77
Teltow 14513
GERMANY

Re: K130785
Trade/Device Names: SEER 1000
Regulatory Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (Two)
Product Code: MWJ
Dated: June 25, 2013
Received: June 28, 2013

Dear Dr. Schadow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K130785

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Indications for Use

510(k) Number (if known):

Device Name: SEER 1000

Indication for Use:

The SEER 1000 is a Holter recorder which is indicated for patients who may benefit from a long-term continuous electrocardiographic (ECG) recording, including, but not limited to, those with complaints of palpitations, syncope, chest pain, shortness of breath, or those that need to be monitored to judge their current cardiac functionality.

Prescription Use __X__ AND/OR Over-The Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation